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K010571

510(k) Summary
Special 510(k): Device Modification

ADC QS/IPD Workstation
For the ADC Computed Radiography System

DEVICE NAME	ADC QS/IPD Workstation	
CLASSIFICATION NAME:	Phosphor Plate Radiographic System - 21CFR 892.1630 The original ADC system has been categorized as 90IXK and is regulated as Class II. The modification involves only the PACS (90LLZ) component of the system.	
TRADE/PROPRIETARY NAME:	Agfa Diagnostic Center or ADC Compact or ADC Solo	
SUBMITTED BY	Agfa Corporation 10 South Academy Street Greenville, SC 29601	864-421-1600
CONTACT PERSON	Jeff Jedlicka	864-421-1815

PERFORMANCE STANDARDS:

The device complies with the relevant international and national Safety Standards. It has been manufactured in compliance with ISO9000 and the Quality System Regulation.

DESCRIPTION OF MODIFICATION:

The ADC QS/IPD is an optional upgrade for the ADC System review stations and will be an eventual replacement product for the existing peripheral devices that are currently part of the ADC System. With the appropriate hardware, the QS/IPD can support a small archive and be used for diagnostic interpretation. The QS/IPD will utilize upgraded hardware and a software revision. The QS/IPD is based on a PC/NT operating system and will encompass three levels of functionality that may be selected by the end user based on need. The levels are Basic QC, QC Viewer and QS/IPD Viewer.

Basic QC level functions allow a minimum set of image manipulations. The QC Viewer will allow the user to have advanced image processing control. The QC workstation has been previously cleared as a component of the existing ADC system. The QS/IPD Viewer will allow all of the above functions and allow the user to operate the workstation as a CR specific PACS station by adding an archive module and high resolution, high brightness monitors.

The ADC QS/IPD is not a mandatory upgrade for existing customers with ADC systems. The current components will continue to be supported. The QS/IPD can, however, be deployed in an existing ADC site without mandatory upgrades of existing components.

EQUIVALENCE INFORMATION:

The ADC Compact was cleared for market on 9 March 1998 (K974597). In September 1998 Agfa notified the Center of a new model, the ADC Solo. At that time Agfa confirmed that the minor mechanical change to implement the new model did not require submission and FDA review (David Segerson for Lillian Yin letter, Sept 22, 1998). References to the ADC Compact throughout this submission, and the applicability of the upgrade apply to both models. They are electrically and functionally identical.

The device is being modified at this time with the upgrade of the software module and an upgrade to hardware accessories to facilitate the use of the device for the diagnostic review of images. The modification does not alter the fundamental scientific technology of the device but does provide necessary hardware capabilities to allow the displayed image to be read without first being transferred to a PACS or printer.

The scope of the modification being submitted includes those changes identified below:

Dimensional specifications (monitor size)
Hardware display resolution
Addition of a hardware image archive
Software / firmware platform

The hardware and software components are used for processing and distributing computed radiographic images on a network. Processing capabilities remain unchanged while the display quality has been increased to allow image review for diagnosis. A hardware accessory can be purchased to allow a small archive for the ADC System.

SAFETY INFORMATION:

This device is identical to the predicate and has identical safety issues and concerns. A summary of the software design description, hazard analysis, and technical and safety information can be found in the attached submission. The results of the hazard analysis, combined with the appropriate measures taken during design and development indicate the device is of minor level of concern, as per the August 29, 1991 issue of the "*Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review*".

Only trained professionals utilize the device and evaluate its output. This allows sufficient review to afford identification and intervention in the event of a malfunction. The device impacts the quality or status of the original acquired image data only in the validated manner described.

Agfa Corporation has demonstrated that the information and data contained in this submission are sufficient for a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2001

AGFA Corporation
C/O T. Whit Athey, Ph.D.
Senior Consultant
C.L. Mcintosh & Associates
12300 Twinbrook PKWY, STE 625
ROCKVILLE MD 20852

Re: K010571
ADC QS/IPD Workstation
Dated: February 23, 2001
Received: February 26, 2001
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Dr. Athey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE

510(k) Number (if known) : K010571

Device Name : ADC QS/IPD Workstation
For ADC Compact and ADC Solo Computed Radiography System

Indications for Use:

To provide diagnostic quality images to aid the physician in diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over the Counter Use _____

David G. Segmm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010571